Double Patenting

Claims 1-93 and 113-127 were provisionally rejected under the judicially created doctrine of double patenting. The Office Action asserts that the subject matter in claims 1-93 and 113-127 is disclosed in U.S. Patent Application Serial No. 09/034,372. The Applicants respectfully submit that the claimed subject matter is not disclosed in 09/034,372. The earlier application is directed toward a specific electrochemical sensor strip. There is not a full disclosure of all aspects of the presently pending claims in that application. In particular, there is no specific disclosure regarding a sensor control unit that is adapted for placement on the skin and which uses an rf transmitter to transmit data obtained using the electrochemical sensor. Accordingly, the Applicants could not prosecute the present claims in U.S. Patent Application Serial No. 09/034,372. The Applicants request withdrawal of this rejection.

Information Disclosure Statement

The Office Action asserts that a copy of each references in the Information Disclosure Statement of July 23, 1998 was not included. The Applicants direct the Examiner to the Information Disclosure Statement which indicates that copies of the references were sent to Examiner Alex Noguerola of Art Unit 1744 with the same Information Disclosure Statement filed for U.S. Patent Application Serial No. 08/795,767. Although that application and the present application are not related, the references in the respective Information Disclosure Statements are the same. One set of references was provided to the U.S. Patent Office to reduce the need for additional storage space. If, however, the Examiner in this case wishes, we will provide an additional set of references. Please contact the Applicants' representative, Bruce E. Black, at 612-371-5348 if you wish to obtain additional copies of the references.

Rejections under 35 U.S.C. §103

Claims 1-30, 32, 40-47, 51, and 122 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,322,063 to Allen et al. (hereinafter "Allen") in view of U.S. Patent No. 5,491,474 to Suni et al. (hereinafter "Suni") and U.S. Patent No. 5,562,713 to Silvian (hereinafter "Silvian"). Claim 31 was rejected under 35 U.S.C. §103(a) as being unpatentable

over Allen in view of Suni, Silvian, and U.S. Patent No. 5,820,551 to Hill et al. (hereinafter "Hill"). Claims 33 and 48 were rejected under 35 U.S.C. §103(a) as being unpatentable over Allen in view of Suni, Silvian, and U.S. Patent No. 5,400,782 to Beaubiah (hereinafter "Beaubiah"). Claims 52-57, 62-78, 89-93, 113-117, 121, 123, and 125-126 were rejected under 35 U.S.C. §103(a) as being unpatentable over Allen in view of Suni, Silvian, and U.S. Patent No. 5,711,861 to Ward et al. (hereinafter "Ward"). Claims 87-88 and 124 were rejected under 35 U.S.C. §103(a) as being unpatentable over Allen in view of Suni, Silvian, Ward, and Hill. The Applicants traverse these rejections for the following reasons.

Allen discloses an electrochemical sensor in which a distal portion of the sensor can be implanted subcutaneously into the body with a proximal portion remaining external from the body. The distal portion includes electrodes and the proximal portion has contacts that are connected by leads to the electrodes. The contacts are then connected to a suitable monitoring device. There is no other detail provided about the monitoring device, as admitted in the Office Action.

Suni discloses a device that includes electrodes for placement on the skin to detect EKG and heartbeat signals. These electrodes are coupled to a transmitter in the device which can relay the signals to a receiver for monitoring the signals. The electrodes and the device do not utilize an electrochemical sensor. Moreover, the entire patient portion of the Suni device rests on the skin of a user. Suni does not teach or suggest the use of an invasive sensor that penetrates the skin of the user.

Silvian discloses an implanted telemetry system for use with an implantable device such as a heart pacemaker. Silvian does not teach or disclose the use of an electrochemical or any other type of sensor. Moreover, there is no disclosure in Silvian regarding a sensor control unit that rests on the skin of a patient and operates using an invasive sensor. The patient portion of the Silvian device is entirely implanted in the patient.

Hill discloses a strip electrode for measuring glucose concentration. The Office Action cites Hill for the use of a thermistor with the strip electrode. There are no details in Hill regarding the placement of the thermistor relative to the electrode and other hardware of the device.

Beaubiah discloses a skin-contacting medical electrode for use in transmitting bio-electric signals between the skin surface and an electrical conductor. Specific uses include transcutaneous electrical nerve stimulating electrodes, iontophoretic electrodes, and electromyographic electrodes. Beaubiah does not disclose the use of invasive electrodes. The entire patient portion of the Beaubiah device rests on the skin of the user.

Ward discloses an implantable glucose sensor. Also implanted with the sensor is a transmitter for sending signals to an external receiver. Ward does not disclose the use of a control device that rests on the skin of a patient and is coupled to an invasive sensor.

As outlined in M.P.E.P. §2143, a *prima facie* case of obviousness requires 1) "some motivation or suggestion, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings", 2) a reasonable expectation of success, and 3) "the prior art reference (or references) must teach or suggest all the claim limitations."

None of the references teach or suggest the Applicants' claimed inventions that include a sensor control unit, having an rf transmitter, that is adapted for placement on skin and for receiving a portion of an electrochemical sensor that extends from the skin, as recited in each of independent claims 1, 46, 121, and 122. The base rejection combines Allen with Suni or Silvian. However, neither Suni nor Silvian are directed to use, with an electrochemical sensor or with a sensor that is implanted, of a sensor control unit having an rf transmitter.

In particular, Silvian is directed to a telemetry system that is implanted in a patient. The Applicants' claims are specifically directed to a sensor control unit that does not need to be implanted. It will be recognized that implantation of a device such as that of Silvian requires surgery. In contrast, the Applicants' disclosed devices can be used by an individual at home. The Applicants' device requires insertion (e.g., subcutaneous insertion) of an electrochemical sensor through the skin and then connecting the sensor to the sensor control unit which mounts on the skin. There is no need for the cost and complications associated with surgery. The insertion of the Applicants' sensor can be accomplished using, for example, an insertion device that is akin to a commonly-used lancet for drawing blood.

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With respect to Suni, the device disclosed in Suni does not need to be coupled to an implanted sensor because the biosignals measured by the device are measurable from the skin. Moreover, there is no need for the complex electrochemical sensor to detect the signals. Thus, there is no need in Suni to consider the complications of combining an implanted sensor with a sensor control unit sitting on the skin.

These differences between Suni and Silvian and the Applicants' inventions illustrate how inappropriate these references are in rejecting the Applicants' claims. Neither reference provides any teaching to those skilled in the art regarding the combination of an implanted electrochemical sensor and a sensor control unit that rests on the skin of a patient.

These substantial differences between the cited references and the Applicants' claimed inventions also highlight the fact that there is no the motivation or suggestion within the references for the combination of the references, as required in M.P.E.P. §2143 to make a *prima facie* case of obviousness. The requirement of motivation or suggestion is necessary to prevent hindsight reconstruction of the invention in view of the Applicants' disclosure. Unfortunately, such a hindsight reconstruction is evident in the rejection of the Applicants' claims. The three references used in the rejection are taken from different areas of art and are used for different, unrelated devices. As stated in M.P.E.P. §2143.01, the "fact that references can be combined or modified is not sufficient to establish *prima facie* obviousness." "Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art." M.P.E.P. §2143.01.

In this case, there is no teaching or suggestion to combine either of the telemetry units of Suni or Silvian with the electrochemical sensor of Allen. Neither Suni or Silvian demonstrate the use of a telemetry unit with an implanted sensor. Neither reference appreciates or teaches the advantages and challenges of combining an implanted sensor with a sensor control unit disposed on the skin. In Silvian, the entire unit is implanted. In Suni, the entire unit sits on the skin and there is no need to consider the challenges of maintaining contact with a sensor that is partially implanted, including having contacts for coupling to contact pads of the sensor. Accordingly,

there is no suggestion or teaching that would suggest to one of ordinary skill in the art to modify Allen to provide a sensor control unit that sits on the skin and has an rf transmitter.

None of the other references, Hill, Beaubiah, or Ward, address these deficiencies of the combination of Allen with Suni or Silvian. In particular, Hill is directed primarily to *in vitro* sensor strips, Beaubiah is directed to a sensor that rests on the skin of a patient as in Suni, and Ward is directed to a surgically implanted sensor.

For at least these reasons, independent claims 1, 24, 121, and 122 are patentable over the cited references, alone or in combination. Dependent claims 2-21, 23, 26-31, 33, 40, 45-92, 113-120, and 123-127 recite other patentable features. These dependent claims are patentable over the cited references for at least the same reasons as claims 1, 24, 121, and 122. The Applicants respectfully request removal of the rejections of claims 1-21, 23, 24, 26-31, 33, 40, 45-92, and 113-127.

Conclusion

In view of the amendments to the claims and the arguments presented herein, the Applicant respectfully submits that each of the presently pending claims (claims 1-21, 23, 24, 26-31, 33, 40, 45-92, and 113-127) is in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' representative at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted,

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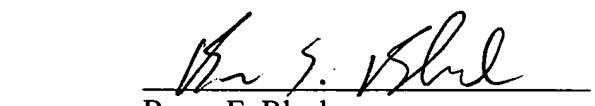

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